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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,330	09/01/2005	Hirofumi Nakamura	Q89815	7031
23373 7590 03/07/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
			EXAMINER PAGE, BRENT T	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 03/07/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/547,330	Applicant(s) NAKAMURA ET AL.	
	Examiner Brent Page	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/2005, 11/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the species *Aspergillus* in the reply filed on 11/08/2007 is acknowledged.

Claims 1-20 are examined herein on the merits.

Claim Objections

Claims 2, 13 and 16 are objected to because of the following informalities: Claim 2 recites nonelected subject matter. Appropriate correction is required. Claims 13 and 16 are objected to because they depend from claim 2.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is broadly drawn to a seed from a transgenic plant. However due to Mendelian inheritance of the transgene, some seeds (~1/4) produced by a transgenic plant will not have a copy of the transgene, and will thus be indistinguishable from naturally occurring seeds. Accordingly, the claims are drawn to a product of nature, which is non-statutory subject matter.

See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo inoculant Co.*, 233 U.S. 127 (1948), and *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931).

This rejection can be overcome by amendment of claim 11 to indicate that the seed comprises said chimeric gene.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the transformation of *Nicotiana* or *Beta vulgaris* with SEQ ID NO:1, does not reasonably provide enablement for the transformation of any plant with any beta-fructofuranosidase from any source, or even any plant with any variant of SEQ ID NO:1 as broadly claimed wherein sucrose would be converted into an fructooligosaccharide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to the transformation of any plant with any beta-fructofuranosidase from any source, or any plant with any variant of SEQ ID NO:1 wherein sucrose would be converted into an fructooligosaccharide.

In contrast the specification only provides guidance for the transformation of tobacco and sugar beet with SEQ ID NO: 1 from *Aspergillus niger*, wherein sucrose is converted into fructooligosaccharides. The specification does not provide guidance for the transformation of any other plants with SEQ ID NO:1 nor does the specification

provide guidance for any other sequences transformed into plants that would convert sucrose into fructooligosaccharides.

The function of different fructosyltransferase genes is unpredictable, and therefore the result of transforming different plants with specific genes in the conversion of sucrose to fructooligosaccharides is also unpredictable. Vergauwen et al (Plant Physiology 2003, 133:391-401) in a review of the role of 1-FFT in Inulin production of different species found that very different degrees of polymerization were found among different species of plants, in particular chicory and globe thistle (see page 391 second full paragraph, and page 399, second and third full paragraphs). Furthermore in a study of the functional domains for fructosyl transferases, Ritsema et al (2004 Plant Molecular Biology 54:853-863) discovered that switching the sucrose binding boxes of FFT, SST, and invertase, along with site directed mutagenesis resulted in different fructosyl transferase activity and function (see page 857 last full paragraph, page 859 last two full paragraphs, for example).

In addition not all beta-fructofuranidase genes have been characterized in all plant species, or for that matter in all other species as broadly claimed and therefore undue experimentation would be required to isolate, sequence, and characterize the enzymatic function of all beta-fructofuranidase genes of all species. The specification also does not provide any guidance for functional domains necessary for beta-fructofuranidase gene function or the amount of conservation in DNA sequence required for activity of the enzyme encoded by the DNA sequences. Without this guidance, undue experimentation would be required to determine all the embodiments of all beta-

fructofuranidase genes that are sufficient to express a protein that produces fructooligosaccharides from a sucrose substrate.

The viability of transgenic plants that accumulate fructan is unpredictable. Turk et al (1997 New Phytology 136:29-38) disclose transgenic tobacco plants transformed with the E. coli levansucrase gene may have deleterious defects in the form of bleached leaves, stunted growth and reduced root growth (see page 36 last paragraph, for example). Caimi et al (WO 95/13389) disclose the lack of viability in shoots of transgenic tobacco plants that were transformed with the bacterial fructosyltransferase gene SacB (see page 68 lines 18-33, for example). Undue experimentation would be required to evaluate all fructosyltransferase coding sequences for their effect on fructan accumulation and plant viability.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to isolate and evaluate all beta-fructofuranidase coding sequences, for their sufficiency to express a protein producing fructooligosaccharides as claimed (see *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984) where a significant number of inoperative embodiments was deemed to indicate an undue amount of experimentation).

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to the transformation of any plant with any beta-fructofuranosidase from any source, or any plant with any variant of SEQ ID NO:1 wherein sucrose would be converted into an fructooligosaccharide.

In contrast the specification only describes the transformation of tobacco and sugar beet with SEQ ID NO: 1 from *Aspergillus niger*, wherein sucrose is converted into fructooligosaccharides. The specification does not describe the transformation of any other plants with SEQ ID NO:1 nor does the specification describe any sequences other than SEQ ID NO:1 transformed into plants that would convert sucrose into fructooligosaccharides.

Furthermore, the specification does not describe which particular sequences of SEQ ID NO:1 are required for functioning as a beta-fructofuranosidase. Without sufficient written description, one of skill in the art would not be able to practice the invention within the full scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-12 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Smeekens et al (WO199601904).

The claims are drawn to a process for producing a transgenic plant which accumulates a fructooligosaccharide comprising transforming a plant a gene construct comprising any gene encoding a beta-fructofuranosidase wherein the gene is operably linked to a constitutive promoter, and organ specific promoter, or a developmental specific promoter wherein the promoter is a sweet potato sporamin promoter, wherein the plant is a dicotyledonous or monocotyledonous plant, wherein the plant belongs to Solanaceae or Beta, a transgenic plant from said process and a seed of the transgenic progeny.

Smeeckens et al teach the transformation of both a sugar beet and a potato with a genetic construct comprising a 6-SFT gene from Barley described in Figure 6A as having beta-fructosidase activity which classifies it as a beta-fructofuranosidase absent evidence to the contrary, wherein the gene is operably linked to the sweet potato sporamin promoter (see Description paragraphs 33-36, for example) which is an organ-specific promoter, Wherein the transgenic plant is produced as well as the seed (see claims for example, as well as description, paragraphs 42-45, for example).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 15 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites a nucleotide sequence having "homology" with that of SEQ ID NO:1. The term "homology" in the specification is defined in paragraph 47 as "a value

obtained by a known program for a homology search". However, as several algorithms are used by BLAST, and as there are several meanings for homology, it is still unclear exactly what "homology" means in the claim and exactly what value that has.

Therefore, it is suggested that Applicant amend the claims to more clearly claim what the intended invention is. New Matter should be avoided. Claims 15 and 18 are rejected as they depend from Claim 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smeekens et al (WO199601904) in view of Yanai et al (US Patent 6337201).

The claims are drawn to the limitations discussed above wherein the beta-fructofuranosidase is from *Aspergillus niger*, and wherein the gene comprises SEQ ID NO: 1, consists of SEQ ID NO: 1, comprises a nucleotide sequence in which one or a plural nucleotides are deleted, substituted, or added in the nucleotide of SEQ ID NO:1, or a gene comprising 85% or more homology with that of SEQ ID NO:1.

Smeekens et al teach the transformation of both a sugar beet and a potato with a genetic construct comprising a 6-SFT gene from Barley described in Figure 6A as having beta-fructosidase activity which classifies it as a beta-fructofuranosidase absent

evidence to the contrary, wherein the gene is operably linked to the sweet potato sporamin promoter (see Description paragraphs 33-36, for example) which is an organ-specific promoter, Wherein the transgenic plant is produced as well as the seed (see claims for example, as well as description, paragraphs 42-45, for example).

Smeeckens et al do not teach that the gene used is from *Aspergillus niger*, but would otherwise meet the limitations as they include sequences with any number of unspecified changes from SEQ ID NO:1. Smeeckens et al also teach the comparison of sequences between plant, bacterial and fungal sources (see the Description of screening a cDNA library, for example).

Yanai et al (US Patent 6337201) teach a sequence with 96.9% identity to SEQ ID NO: 1 which is from *Aspergillus niger*.

Given the state of the art and the disclosures by Smeeckens et al and Yanai et al, it would have been obvious to one of ordinary skill in the art to modify the method and transformation taught by Smeeckens et al by using the sequence taught by Yanai et al, as suggested by Smeeckens et al.

No claims are free of the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (571)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

RUSSELL P. KALLIS, PH.D.
PRIMARY EXAMINER

Russell P. Kallis